AUG 0 6 2009

SUMMARY OF SAFETY AND EFFECTIVENESS

Assigned 510(k) Number

The assigned 510(k) number is K091289.

Sponsor Name and Address

Siemens Healthcare Diagnostics Inc.
5210 Pacific Concourse Drive
Los Angeles, CA
90045-6900
(310) 645-8200

Contact

Clare Santulli
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Device Name

Trade name:	IMMULITE® 2000 3gAllergy™ Specific IgE Assay
Classification:	Class II
Classification Names:	Radioallergosorbent (RAST) Immunological Test System
Regulation Number:	866.5750
Product Code:	DHB
Catalog Numbers:	L2KUN6 (600 tests)

Description of Device

IMMULITE® 2000 3gAllergy™ Specific IgE is a solid-phase, two-step, chemiluminescent immunoassay that exploits liquid phase kinetics in a bead format.[1,2] (U.S. Patent No. 4,778,751) It represents a significant advance over conventional methods relying on allergens attached to a solid-phase support, such as a paper disk.

The allergens are covalently bound to a soluble polymer/co-polymer matrix, which in turn is labeled with a ligand. The use of an amino acid co-polymer amplifies the amount of allergen that the matrix can support.

Incubation Cycles: 2 × 30 minutes.

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[1] El Shami AS, Alaba O. Liquid-phase *in vitro* allergen-specific IgE assay with *in situ* immobilization. Adv Biosci 1989;74:191–201.

[2] Alaba O, El Shami AS. Evaluation of non-specific IgE binding: comparison of two *in vitro* allergen assays. Adv Biosci 1989;74:203–14.

Indications for Use

For *in vitro* diagnostic use with the IMMULITE® 2000 Analyzer — for the quantitative measurement of allergen-specific IgE in human serum, as an aid in the clinical diagnosis of IgE-mediated allergic disorders.

Establishment Information

IMMULITE® 2000 3gAllergy Specific IgE assay is manufactured by Siemens Healthcare Diagnostics Inc. at the following locations:

Siemens Healthcare Diagnostics Inc.
5210 Pacific Concourse Drive
Los Angeles, CA 90045-6900
FDA Establishment #: 3005250747

Predicate

The purpose of this 510(k) submission is for clearance of seven additional specific allergens, named in the table below, to be used with the IMMULITE® 2000 3gAllergy™ Specific IgE on the IMMULITE® 2000 analyzer.

1	**K84**	**Sunflower Seed**
2	**M207**	**Aspergillus niger**
3	**M202**	**Cephalosporium acremonium**
4	**T96**	**Poplar**
5	**W82**	**Careless Weed**
6	**W37**	**Saltbush**

FDA clearance was previously obtained for the assay kit and 196 specific allergens and allergen panels (K013134, K021206, K013135 and K021208).

Please note that the FDA clearances indicated above were in the name of Diagnostic Products Corporation which was acquired by Siemens Medical Solutions Diagnostics in July 2006. Siemens Medical Solutions Diagnostics was renamed Siemens Healthcare Diagnostics Inc. on January 1, 2008.

Precision

Precision studies were performed in accordance with Clinical Laboratory Standard Institute (CLSI) guidance: *Evaluation of Precision Performance of Quantitative Methods; Approved Guideline-Second Edition.* CLSI document EP5-A2 (ISBN 1-56238-542-9). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004, assaying two aliquots of each test sample in two runs per day on 20 different days. Analysis of variance was used to estimate the within-run and total precision.

Three allergen lots were tested using three positive samples and one negative sample. Intra-assay and inter-assay precision for the positive samples were evaluated by calculating the

kU/L dose percent coefficients of variation (%CV) for each positive sample. Non-specific binding (NSB) was monitored by testing the negative control sample.

A fourth positive sample was evaluated for allergens Poplar and Careless Weed to ensure acceptable precision performance in the high end of the assay range.

Representative precision claims for each allergen tested are presented below:

Allergen Precision Claims*

Sample	Mean kU/L	Within-Run SD kU/L	Within-Run CV %	Total SD kU/L	Total CV %
Allergen = Sunflower Seed, Lot 114					
Positive #1	0.56	0.034	6.07	0.055	9.82
Positive #2	1.26	0.047	3.73	0.067	5.32
Positive #3	10.42	0.457	4.39	0.648	6.22
Allergen = Aspergillus niger, Lot 115					
Positive #1	1.45	0.061	4.21	0.102	7.03
Positive #2	4.36	0.210	4.82	0.407	9.33
Positive #3	2.67	0.103	3.86	0.220	8.24
Allergen = Cephalosporium acremonium, Lot 115					
Positive #1	1.49	0.049	3.29	0.077	5.17
Positive #2	1.22	0.051	4.18	0.060	4.92
Positive #3	0.86	0.030	3.49	0.053	6.16
Allergen = Poplar, Lot 111					
Positive #1	9.99	0.326	3.26	0.541	5.42
Positive #2	4.22	0.143	3.39	0.249	5.90
Positive #2	2.69	0.097	3.61	0.223	8.29
Positive #4	68.29	2.101	3.08	3.135	4.59
Allergen = Careless Weed, Lot 113					
Positive #1	16.52	0.495	3.00	0.962	5.82
Positive #2	1.94	0.082	4.23	0.097	5.00
Positive #3	3.51	0.096	2.74	0.160	4.56
Positive #4	41.58	0.996	2.40	2.246	5.40
Allergen = Saltbush, Lot 112					
Positive #1	2.63	0.078	2.97	0.108	4.11
Positive #2	0.79	0.027	3.42	0.032	4.05
Positive #3	4.72	0.174	3.69	0.236	5.00

* data are representative of one lot on one instrument

Linearity

For each allergen, two samples were diluted in 2-fold serial dilutions to 5 levels. The undiluted (neat) and diluted samples were tested with the specific allergen to demonstrate

linearity at concentrations within the assay limits. Regression statistics for each allergen comparing observed to expected data are presented below.

Linearity

Allergen	Regression Equation	N	Slope	95% CI	Intercept	95% CI
Sunflower Seed	Y= 0.999X -0.023	12	0.999	0.986–1.012	–0.023	–0.059-0.014
Aspergillus niger	Y= 0.989X +0.025	12	0.989	0.970–1.007	0.025	–0.032-0.083
Cephalosporium acremonium	Y= 0.961X +0.059	8	0.961	0.939–0.983	0.059	0.045 –0.073
Poplar	Y= 1.00X – 0.043	12	1.002	0.963–1.042	–0.043	–0.124-0.038
Careless Weed	Y= 1.013X –0.040	12	1.013	0.990–1.036	–0.040	–0.227-0.147
Saltbush	Y= 1.00X – 0.030	12	1.002	0.989–1.015	0.030	–0.019-0.078

Specificity (Inhibition) Studies

Specificity of each allergen was verified through competitive inhibition testing using a single serum sample or pool of sera. A negative sample was used to measure the background response.

To initiate the inhibition experiment, 70µL of undiluted and 4 levels of 5-fold serially diluted inhibitor extract were mixed with 250µL of sample or pool. This mixture was incubated at room temperature (15-28 °C) for 1 hour allowing the immunological reaction to occur. Each sample mixture containing the inhibitor extract and the appropriate controls was assayed with 1 lot of each allergen. The percent (%) inhibition was calculated according to the following formula:

$$\frac{(\text{Response of pos. control}_{(\text{pos. sample - neg. sample})} - \text{sample response with inhibitor extract})}{(\text{Response of pos. control}_{(\text{pos. sample - neg. sample})})} \times 100$$

The inhibition study demonstrated that the allergens tested are inhibited by the relevant inhibitor extract in a concentration dependent fashion. Also, the target % inhibition of 50% was met. These results indicate specificity of Sunflower Seed, Aspergillus niger, Cephalosporium acremonium, Poplar, Careless Weed, and Saltbush specific allergens. Summary inhibition table is presented below.

Sunflower Seed		Aspergillus niger		Cephalosporium acremonium

Inhibitor Concentration (mg/mL)	% Inhibition		Inhibitor Concentration (mg/mL)	% Inhibition		Inhibitor Concentration (mg/mL)	% Inhibition
5	96.89		5	95.91		5	81.53
1	94.53		1	94.01		1	83.33
0.2	46.77		0.2	90.46		0.2	80.18
0.04	19.15		0.04	80.93		0.04	43.69
0.008	6.59		0.008	65.67		0.008	34.68
			0.0016	37.87			
Poplar			**Careless Weed**			**Saltbush**	
5	100.00		5	100.00		5	100.00
1	96.17		1	98.57		1	83.96
0.2	86.17		0.2	95.53		0.2	59.89
0.04	56.81		0.04	83.63		0.04	28.34
0.008	37.66		0.008	49.10		0.008	12.30

Clinical Performance Studies

Clinical performance of Sunflower Seed, Aspergillus niger, Cephalosporium acremonium, Poplar, Careless Weed, and Saltbush allergens was demonstrated by testing samples from non-atopic individuals and samples from atopic patients with case histories of suspected clinical reactions to the specific allergen or allergy group in the IMMULITE® 2000 3gAllergy Specific IgE assay and comparing results to accompanying clinical information.

Data summary agreement of the IMMULITE® 2000 3gAllergy results to clinical data is presented in the table below.

IMMULITE® 2000	Clinical Data				
	Clinical	Normal	Total		
Positive	135	28	163		

Negative	154	611	765		
Total	289	639	928		
	46.7%	95.6%	80.4%		
	Sensitivity	Specificity	Agreement		
Lower Conf	**41%**	**94%**	**78%**		
Upper Conf	**52%**	**97%**	**83%**		
Allergens included: Sunflower Seed, Aspergillus niger, Cephalosporium acremonium, Poplar, Careless Weed, and Saltbush					

IMMULITE® 2000 3gAllergy assay results for all allergens compare well with clinical documentation of presence or absence of signs, symptoms and other diagnostic evidence of allergen sensitivity.

Conclusions for all Studies

Allergens including Sunflower Seed, Aspergillus niger, Cephalosporium acremonium, Poplar, Careless Weed, and Saltbush for use with the IMMULITE® 2000 3gAllergy Specific IgE assay demonstrate acceptable analytical performance including precision, linearity and specificity. IMMULITE® 2000 assay results compare well with clinical documentation of presence or absence of signs, symptoms and other diagnostic evidence of allergen sensitivity. Substantial equivalence was demonstrated to clinical data, supporting the following intended use of the IMMULITE® 2000 3gAllergys Specific IgE assay and the six previously listed allergens:

> For *in vitro* diagnostic use with the IMMULITE® 2000 Analyzer — for the quantitative measurement of allergen-specific IgE in human serum, as an aid in the clinical diagnosis of IgE-mediated allergic disorders.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Siemens Healthcare Diagnostics
c/o Clare Santulli
Sr. Regulatory Affairs Specialist
511 Benedict Avenue
Tarrytown, New York 10591

AUG 0 6 2009

Re: k091289
Trade/Device Name: IMMULITE® 2000 3gAllergy ™ Specific IgE Assay
Regulation Number: 21 CFR 866.5750
Regulation Name: Radioallergosorbent (RAST) Immunological Test System
Regulatory Class: II
Product Code: DHB
Dated: April 29, 2009
Received: May 7, 2009

Dear Ms. Santulli,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): 091289

Device Name: IMMULITE 3gAllergy™ Specific IgE Assay

Indication For Use:

For *in vitro* diagnostic use with the IMMULITE 2000 Analyzer — for the quantitative measurement of allergen-specific IgE in human serum, as an aid in the clinical diagnosis of IgE-mediated allergic disorders.

Prescription Use ___√___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Maria M Chan

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 091289